

Attorney's Docket No. MPI1998-067CP1CN. (M)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Sophie Lehar, Stephen Manning, Anthony J. Coyle, Jose-Carlos Gutierrez-Ramos  
Application No.: N/A Group No.: \*\*\*Not Assigned\*\*\*  
Filed: Herewith Examiner: \*\*\*Not Assigned\*\*\*  
For: NOVEL TH2-SPECIFIC MOLECULES AND USES THEREOF

Assistant Commissioner for Patents  
Washington, D.C. 20231

PATENT

1c978 U.S. PTO  
09/989545



TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. section 1.97(b))

Transmitted herewith are:

- ☒ Transmittal letter (1 page)(in duplicate).
- ☒ Information Disclosure Statement (3 pages).
- ☒ Form PTO/SB/08A (1 page).
- ☒ Form PTO/SB/08B (2 pages).
- ☒ 9 References.

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

Express Mail" mailing label number <u>EL791759296US</u>	<b>MILLENNIUM PHARMACEUTICALS, INC.</b>  By <u>Kerri Pollard Schray</u> Kerri Pollard Schray Registration No.: 47,066 Agent for Applicants Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge, MA 02139 Telephone: 617-551-3676 Facsimile: 617-551-8820
Date of Deposit <u>November 20, 2001</u>	
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Box Sequence, Washington, D.C. 20231	
Signature <u>Sean Hunziker</u>	
Please Print Name of Person Signing <u>Sean Hunziker</u>	

Attorney's Docket No. MPI1998-067CP2CN1A(M)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

PATENT

10978 U.S. PTO  
09/989545  
11/20/01

In re application of: Sophie Lehar, Stephen Manning, Anthony J. Coyle, Jose-Carlos Gutierrez-Ramos

Application No.: N/A

Group No.: \*\*\*Not Assigned\*\*\*

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Examiner: \*\*\*Not Assigned\*\*\*

For: NOVEL TH2-SPECIFIC MOLECULES AND USES THEREOF

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

**List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

1. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)
2. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
3. Copies of Listed Information Items Accompanying This Statement
4. Identification of Person(s) Making This Information Disclosure Statement

**Section 1. Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)**

(Insert form(s) PTO/SB/08A [Form 6-2] and/or form(s) PTO/SB/08B [Form 6-2.1].)

**Section 2. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted**

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN.: 09/413,136, filed on October 6, 1999.

This application also relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN: 09/258,670, filed on February 26, 1999.

This application also relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN 09/168,229, filed on October 7, 1998.

The following references were submitted to, and/or cited by, the Office in the prior applications and, therefore, are not required to be provided in this application:

US 5,783, 182	Baylor College of Medicine	07/21/1998
WO 98/38216	Japan Tobacco Inc.	09/03/1998
WO 98/39448	Human Genome Sciences, Inc.	09/11/1998
WO 98/45437	Genetics Institute, Inc.	10/15/1998
WO 99/07727	Massachusetts Institute of Technology	02/18/1999
WO 99/09049	Quark Biotech, Inc. et al.	02/25/1999
WO 99/46281	Genentech, Inc.	09/16/1999

ROBINSON et al., Predominant TH2-Like Bronchoalveolar T-Lymphocyte Population in Atopic Asthma, The New England Journal of Medicine, January 30, 1992, 298-304, Vol. 326(5), USA

ROMAGNANI, S., Induction of TH1 and TH2 Responses: A Key Role for the 'Natural' Immune Response?, Immunology Today, 1992, 379-381, Vol. 13(10), Elsevier Science Publishers Ltd., United Kingdom

DEL PRETE et al., Allergen Exposure Induces the Activation of Allergen-specific Th2 Cells in the Airway Mucosa of Patients with Allergic Respiratory Disorder, European Journal of Immunology, 1993, 1445-1449, Vol. 23, VCH Verlagsgesellschaft mbH, Weinheim

TAO et al., Strength of TCR Signal Determines the Costimulatory Requirements for Th1 and Th2 CD4+ T Cell Differentiation, The Journal of Immunology, 1997, 5956-5963, The American Association of Immunologists.

NICOLAIDES et al., Interleukin 9: A Candidate Gene for Asthma, Proc. Natl. Acad. Sci. USA, November 1997, 13175-13180, Vol. 94, Medical Sciences.

MORIGGL et al., Activation of STAT Proteins and Cytokine Genes in Human Th1 and Th2 Cells Generated in the Absence of IL-12 and IL-4, The Journal of Immunology, 1998, 3385-3392, The American Association of Immunologists.

PADRID et al., CTLA4Ig Inhibits Airway Eosinophilia and Hyperresponsiveness by Regulating the Development of Th1/Th2 Subsets in a Murine Model of Asthma, American Journal of Respiratory Cell and Molecular Biology, 1998, 453-462, Vol. 18, USA

SMITH et al., Partial TCR Signals Delivered by FcR-Nonbinding Anti-CD3 Monoclonal Antibodies Differentially Regulate Individual Th Subsets, The Journal of Immunology, 1998, 4841-4849, The American Association of Immunologists.

DATABASE GenBank on STN Accession No. AA21744, MARRA et al., T wash U-HHM1 Mouse EST Project, January 21, 1997

HUANG, S-K, Molecular Modulation of Allergic Responses, J. Allergy Clin. Immunol., December 1998, 887-892, Vol. 102

GAP Alignment of h1419 vs. V59728 in WO 98/39448

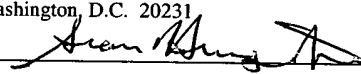
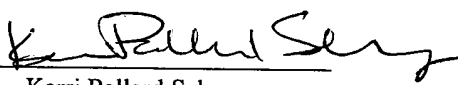
**Section 3. Copies of Listed Information Items Accompanying This Statement**

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement except these listed in Section 2.

**\*\*\*IF GF6-1 Language Listed Info = "EPO Search Report"\*\*\*\*\*IF GF6-1 Language Listed Info = "English Language Version of EPO Search Report"\*\*\*\*Section 4. Identification of Person Making This Information Disclosure Statement**

The person making this certification is:

- a. the practitioner who signs below on the basis of the information in the practitioner's file.

<p>Express Mail" mailing label number <u>EL791759296US</u></p> <p>Date of Deposit <u>November 20, 2001</u></p> <p>I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231</p> <p> Signature</p> <p><u>Sean Hunziker</u> Please Print Name of Person Signing</p>	<p>MILLENNIUM PHARMACEUTICALS, INC.</p> <p>By  Kerri Pollard Schray Registration No.: 47,066 Agent for Applicants Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge, MA 02139 Telephone: 617-551-3676 Facsimile: 617-551-8820</p>
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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	1
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**Complete if Known**

<b>Application Number</b>	N/A
<b>Filing Date</b>	11/21/2001
<b>First Named Inventor</b>	Sophie Lehar et al
<b>Group Art Unit</b>	
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	MP11998-067CP2CN1A(M)

U.S. PTO

11/20/01

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>2</sup>	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>  (if known)				
	2	WO	98/38216	Japan Tobacco Inc.	03/09/1998		
	3	WO	98/39448	Human Genome Sci	09/11/1998		
	4	WO	98/45437	Genetics Institute	10/15/1998		
	5	WO	99/07727	Mass Inst of Techn	02/18/1999		
	6	WO	99/09049	Quark Biotech, Inc	02/25/1999		
	7	WO	99/46281	Genentech, Inc.	09/16/1999		
	8	WO	99/15553	Robert Koch Instit	04/01/1999		
	9	EP	0984023	Japan Tobacco Inc.	03/08/2000		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

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PTO/SB/08B (10-96)

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1

of 2

### Complete if Known

Application Number N/A  
Filing Date 11/20/2001  
First Named Inventor Sophie Lehar et al  
Group Art Unit  
Examiner Name  
Attorney Docket Number MPI1998-067CP2CN1A(M)

10978 U.S. PRO  
11/20/01

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	11	ROBINSON ET AL, "Predominant TH2-Like Bronchoal Veolar T-Lymphocyte Population in Atopic Asthma," The NE Journal of Medicine, Vol. 326 ( No. 5), p. 298-304, ( January 30, 1993).	
	12	ROMAGNANI, S., "Induction of TH1 and TH2 Responses: A Key Role for the 'Natural' Immune Response?," Immunology Today, Elsevier Science Publishers Ltd. United Kingdom, Vol. 13 ( No. 10), p. 379-381, ( November 20, 1992).	
	13	DEL PRETE ET AL., "Allergen Exposure Induces the Activation of Allergen-specific Th2 Cells in the Airway Mucosa of Patients with Allergic Respiratory Disorder," European Jour of Immunology, p. 1445-1449, ( November 20, 1993).	
	14	TAO ET AL., "Strength of TCR Signal Determines the Costimulatory Requirements for Th1 and Th2 CD4+ T Cell Differentiation," The Jour of Immunology, p. 5956-5963, ( November 20, 1997).	
	15	NICOLAIDES ET AL., , "Interleukin 9: A Candidate Gene for Asthma," Proc. Natl. Acad. Sci., p. 13175-1318, ( November 20, 1997).	
	16	MORIGGL ET AL., "Activation of STAT Proteins and Cytokine Genes in Human Th2 and Th2 Cells Generated in the Absence of IL-12 and IL-4," The Jour of Immunology, p. 3385-3392, ( November 20, 1998).	
	17	PADRID ET AL., "CTLA4Ig Inhibits Airway Eosinophilia and Hyperresponsiveness by Regulating the Development of Th1/Th2 Subsets in a Murine Model of Asthma," Amer Jour of Respiratory Cell and Molecular Biology, p. 453-462, ( November 20, 1998).	
	18	SMITH ET AL., "Partial TCR Signals Delivered by FcR-Nonbinding Anti-CD3 Monoclonal Antibodies Differentially Regulate Individual Th Subsets," The Jour of Immunology, p. 4841-4849, ( November 20, 1998).	
	19	DATABASE GENBANK ON STN ACCESSION NO. AA21744, MARRA ET AL., T WASH U-HHMI MOUSE EST PROJECT, ", ( January 21, 1997).	
	20	HUANG, S-K, "Molecular Modulation of Allergic Responses," J. Allergy Clin. Immunol., p. 887-892, ( December 20, 1998).	
	21	GAP Alignment of h1419 vs. V59728 in WO 98/39448	

Examiner  
Signature

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<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	N/A
		Filing Date	11/20/2001
		First Named Inventor	Sophie Lehar et al
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	MPI1998-067CP2CN1 (M)
Sheet 2	of 2		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
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	22	HUTLOFF, A. ET AL, "ICOS is an inducible T-Cell co-stimulaor structurally and functionally related to CD28," Nature, p. 263-266, ( January 21, 2000).	
	23	BUONFIGLIO, D. ET AL, "The T Cell Activation Molecule H4 and the CD28-Like Molecule ICOS are Identical," Eur. J. Immunol., p. 3463-3467, ( November 20, 2000).	
	24	BUONFIGLIO, D. ET AL., "Characterization of a Novel Human Surface Molecule Selectively Expressed by Mature Thymocytes, Activated T Cells and Subsets of T Cell Lymphomas," Eur. J. Immunol., p. 2863-2874, ( November 20, 1999).	
	25	REDOGLIA, V., ET AL., "Characterization of H4: A Mouse T Lymphocyte Activation Molecule Functionally Associated with the CD3/T Cell Receptor," Eur. J. Immunol., p. 2781-2789, ( November 20, 1996).	
	26	GONZALO, J. ET AL., "ICOS is Critical for T Helper Cell-Mediated Lung Mucosal Inflammatory Responses," Nature Immunology, Vol. 2 ( No. 7), p. 597-604, ( July 20, 2001).	
	27	ROTTMAN, J. ET AL., "The Costimulatory Molecule ICOS Plays an Important Role in the Immunopathogenesis of EAE," Nature Immunology, Vol. 2 ( No. 7), p. 605-611, ( July 20, 2001).	
	28	OZKAYNAK, E. ET AL., "Importance of ICOS-B7RP-1 Costimulation in Acute and Chronic Allograft Rejection," Naure Immunology, Vol. 2 ( No. 7), p. 591-596, ( July 20, 2001).	

Examiner Signature		Date Considered	
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